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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,449	09/21/2001	Troy Holland	BioCure 161	5786
27029	7590	04/02/2004	EXAMINER	
BIOCURE, INC. 2975 GATEWAY DRIVE SUITE 100 NORCROSS, GA 30071			GHALL, ISIS A D	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/960,449	Applicant(s) HOLLAND ET AL.	
	Examiner Isis Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,8-11,13-17,21-23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,8-11,13-17,21-23 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request under 1.114, both filed 02/19/2004.

Claims 1-4, 8-11, 13-17, 21-23 and 25 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/19/2004 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, 8, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,007,833 (833).

The scope of claim 1 covers a liquid composition comprising a water soluble PVA having one or more pendant crosslinkable acrylamide groups. The intended use of the composition for spray delivery is not given weight in a claim directed to a composition.

US '833 disclosed a hydrogel wound dressing that is applied to the wound site as a liquid composition and forms flexible polymeric matrix upon exposure to light, i.e. hydrogel formed *in situ* (col.10, lines 1-6). The hydrogel composition comprising crosslinkable macromer includes two or more polymer pendant polymerizable group (abstract). The macromer includes water-soluble polymer, i.e. degradable, as polyvinyl alcohol; and acrylamide as a pendant polymerizable group (col.5, lines 25-30, 47-53). Acrylamide groups inherently contain olefinically unsaturated groups. The hydrogel comprises therapeutic agent including growth factor, antimicrobial agent and antithrombotic agent (col.10, lines 11-12, 35-37).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 3, 4, 10, 11, 13-17, 21-23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,007,833 ('833) in view of US 6,179,862 ('682).

US '833 teaches a hydrogel wound dressing that is applied to the wound site as a liquid composition and forms flexible polymeric matrix upon exposure to light, i.e. hydrogel formed *in situ* (col.10, lines 1-6). The hydrogel composition comprising crosslinkable macromer includes two or more polymer pendant polymerizable group (abstract). The macromer includes water-soluble polymer, i.e. degradable, as polyvinyl alcohol; and acrylamide as a pendant polymerizable group (col.5, lines 25-30, 47-53). The hydrogel comprises therapeutic agent including growth factor and antimicrobial agent (col.10, lines 11-12).

US '833 does not teach the composition is delivered by spray as claimed in claims 3, 4, 14-17, 21-22. The reference does not teach the active agent as NO as claimed in claims 10 and 23, or the redox irradiation as claimed in claims 13 and 25.

The reference does not teach the dressing debrides the wound when removed as claimed in claim 12.

However, US '833 teaches the liquid delivery of the composition without excluding or specifying any method of delivery, thus the spraying the liquid composition into the wound is inclusive in the reference teaching. The reference also teaches the delivery of antithrombotic drugs at the site of application, and this is inclusive to NO, and one having ordinary skill in the art would have determined the antithrombotic agent to use according to the specific patient condition. The reference further teaches the UV irradiation to initiate polymerization. The reference disclosed that the wound dressing formed is very well adheres to the wound site, and it is expected upon its removal to debride the wound.

US '862 disclosed method and composition for forming *in situ* tissue adherent barrier using sprayer to apply cross-linkable two components to the tissue that enable to form coating on the tissue surface (abstract; col.1, lines 48-51, 65-67; col.2, lines 1-8). When the sprayer is activated, the emergent spray contacts tissue, resulting in mixing and cross-linking of the components to form coating, e.g. hydrogel, on the tissue surface (col.2, lines 5-9). The components are in the form of solution and comprise water-soluble, crosslinkable, biodegradable macromers (col.2, lines 19-34; col.7, lines 24-30). The hydrogel formation is initiated by redox irradiation to form coating (col.4, lines 24-27; col.6, lines 3-5).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a hydrogel composition comprising crosslinkable

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macromer includes two or more polymer pendant polymerizable group of acrylamide as disclosed by US '833 and deliver the composition by spraying and use redox for crosslinking as disclosed by US '862, motivated by the teaching of US '862 that the spraying on the tissue surface followed by redox irradiation enable to form a wound coating, with reasonable expectation of having a hydrogel composition comprising crosslinkable macromer includes two or more polymer pendant polymerizable group that is delivered from sprayer and polymerized by redox irradiation that enables to protect the wound and initiate wound healing with success.

Response to Arguments

7. Applicant's arguments with respect to claims 1-4, 8-11, 13-17, 21-23 and 25 have been considered but are moot in view of the new ground(s) of rejection.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

Isis Ghali

